



Ensuring Medical Device
Safety and Compliance™

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Dockets Management Branch, HFA 305
Food Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Sir/Madame,

Re: Medical Gloves; Draft guidance Manual (Document No. 99D-2335)

I would like to offer comments on this document published in the Federal Register (July 30, 1999: Vol. 64, No. 146, p4174) specifically in regard to Part 5 Biocompatibility. In general, this section is very similar to past issues of this guideline. Unfortunately, manufacturers and importers see this document as a vertical standard that supersedes other recognized medical device biocompatibility standards that should be considered when evaluating gloves as a medical device.

Most of the requirements in this document are focused on protecting the healthcare worker who wears the gloves for examinations and treatments, and the contact is strictly to the hands and wrists. This guideline has historically overlooked the patient exposure aspects of gloves as devices. When considered from the patient's perspective, the exposure may be to intact or abraded skin, may be to mucosal tissue, to visceral organs, to the brain and/or cerebral spinal fluid, or to bone. Exposure occurs during clinical or surgical procedures. Some contact may last up to 8 hours. Exposure could be at multiple intervals and may involve multiple gloved surgeons and nurses that tend to exaggerate the contact (i.e. not just one pair of gloves making the contact with the patient). In these circumstances, it is necessary to categorize the contact as in the matrix found in ISO 10993-1: Evaluation and Testing, or the FDA adaptation GP#95-1. The Primary Skin Irritation dermal patch test and the Delayed Contact Sensitization Test by the Buehler patching method would be inadequate.

Medical gloves are unique: there is both the potential for harm from repeated exposure to healthcare worker hands, and from the surgical or treatment exposures to patients. The testing program to establish biocompatibility must account for both.

If I can be of any service discussing this program further, please feel free to contact me. Otherwise, I would recommend that you consult Dr. Raju Kammula of CDRH as an FDA contact who would realize the significance of this suggestion.

Lastly, I suggest that you not list the laboratories capable of doing these tests, unless it is made clear which do human studies, which do non clinical testing, and which claim to do medical device work. As it now stands, it is quite confusing. Any laboratory that does chemical testing can patch test sections of gloves to rabbits for the skin irritation tests, and most likely can do the guinea pig patching as well. However, many of the laboratories listed are not recognized as capable of testing gloves as devices.

Sincerely,

Paul J. Upman, Ph.D.
Senior Scientist

cc: R. Kammula

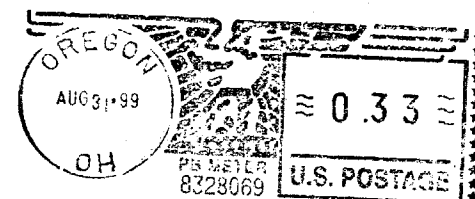
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